Amendment and Response dated May 18, 2005

Amendment and Response to November 18, 2004 Office Action

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-13 (cancelled)

- Claim 14 (Currently amended): A method of treating a disease or injury induced by pathological free radical reactions in a mammal exposed to a caustic gas, the method comprising administering to a <u>the</u> mammal an effective amount of an amphipathic antioxidant composition comprising:
 - (i) a population of liposomes suitable for undergoing peroxidation and lysis; and
 - (ii) at least two non-enzymatic, amphipathic antioxidants,

wherein the amphipathic antioxidant composition quenches free radicals and reduces the damage induced by the caustic gas exposure.

- Claim 15 (Previously presented): The method of claim 14, wherein said non-enzymatic antioxidants are selected from the group consisting of: beta-carotene, vitamin E, vitamin C, glutathione, niacin, and N-acetyl-cysteine.
- Claim 16 (Previously presented): The method of claim 14, wherein at least one of the non-enzymatic antioxidants is hydrophilic and at least one of the non-enzymatic antioxidants is hydrophobic.
- Claim 17 (Previously presented): The method of claim 14, wherein said composition further comprises at least one trace metal.
- Claim 18 (Previously presented): The method of claim 17, wherein said at least one trace metal is selected from the group consisting of zinc, selenium, chromium, copper and manganese.
- Claim 19 (Previously presented): The method of claim 14, wherein said composition further comprises a pharmaceutically acceptable carrier.

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- Claim 20 (Previously presented): The method of claim 14, wherein said composition is administered by a route of administration selected from the group consisting of: intravenous, intraperitoneal, subcutaneous, intramuscular, intraarticular, intraarterial, intracerebral, intracerebellar, intrabronchial, intrathecal, topical, and aerosol route.
- Claim 21 (Currently amended): A method of treating a disease or injury induced by pathological free radical reactions in a mammal exposed to a caustic gas, the method comprising administering to a <u>the</u> mammal an effective amount of an amphipathic antioxidant composition comprising:
 - (i) a population of liposomes suitable for undergoing peroxidation and lysis; and
 - (ii) <u>at least two non-enzymatic amphipathic antioxidants selected from the group</u>
 <u>consisting of:</u> beta-carotene, vitamin E, vitamin C, glutathione, <u>N-acetyl-cysteine</u>,
 and niacin,

wherein the amphipathic antioxidant composition quenches free radicals and reduces the damage induced by the caustic gas exposure.

- Claim 22 (Previously presented): The method of claim 21, wherein said amphipathic antioxidant composition further comprises at least one trace metal.
- Claim 23 (Previously presented): The method of claim 22, wherein said at least one trace metal is selected from the group consisting of zinc, selenium, chromium, copper and manganese.
- Claim 24 (Currently amended): The method according to claim 22, wherein composition includes an amount of beta-carotene, vitamin E, vitamin C, glutathione, niacin, and trace metals sufficient to deliver 0.0005-1.0 g beta-carotene per kg body weight, 0.001-10 g vitamin E per kg body weight, 0.001-2.0 g vitamin C per kg body weight, 0.001-2.0 g glutathione per kg body weight, 0.003-6.0 g N-acetyl-cysteine per kg body weight, 1-1000 mg niacin per day, and 1-1000 µg trace metals per day.
- Claim 25 (Currently amended): The method according to claim 22, wherein the composition includes an amount of beta-carotene, vitamin E, vitamin C, glutathione, niacin, and trace

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metals sufficient to deliver 0.005-1.0 g beta-carotene per kg body weight, 0.01-1.0 g vitamin E per kg body weight, 0.01-1.0 g vitamin C per kg body weight, 0.01-1.0 g glutathione per kg body weight, 0.003-6.0 g N-acetyl-cysteine per kg body weight, 10-100 mg niacin per day, and 10-100 µg trace metals per day.

- Claim 26 (Currently amended): The method according to claim 22, wherein the composition includes an amount of beta-carotene, vitamin E, vitamin C, and glutathione sufficient to deliver 0.05-1.0 g beta-carotene per kg body weight, 0.1-1.0 g vitamin E per kg body weight, 0.1-1.0 g vitamin C per kg body weight, 0.1-1.0 g glutathione per kg body weight, 0.003-6.0 g N-acetyl-cysteine per kg body weight, 10-100 mg niacin per day, and 10-100 µg trace metals per day.
- Claim 27 (Currently amended): A method for reducing the deleterious effects of pathological free radical reactions in a mammal with a disease or injury induced by exposure to a caustic gas, the method comprising administering an effective amount of an amphipathic antioxidant composition comprising:
 - (i) a population of liposomes suitable for undergoing peroxidation and lysis; and
 - (ii) at least two non-enzymatic, amphipathic antioxidants,

wherein the amphipathic antioxidant composition quenches free radicals and reduces the damage induced by the caustic gas exposure.

- Claim 28 (Previously presented): The method of claim 27, wherein said non-enzymatic antioxidants are selected from the group consisting of: beta-carotene, vitamin E, vitamin C, glutathione, niacin, and N-acetyl-cysteine.
- Claim 29 (Previously presented): The method of claim 27, wherein at least one of the nonenzymatic antioxidants is hydrophilic and at least one of the non-enzymatic antioxidants is hydrophobic.
- Claim 30 (Previously presented): The method of claim 27, wherein said composition further comprises at least one trace metal.

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- Claim 31 (Previously presented): The method of claim 30, wherein said at least one trace metal is selected from the group consisting of zinc, selenium, chromium, copper and manganese.
- Claim 32 (Previously presented): The method of claim 27, wherein said composition further comprises a pharmaceutically acceptable carrier.
- Claim 33 (Previously presented): The method of claim 27, wherein said composition is administered by a route of administration selected from the group consisting of: intravenous, intraperitoneal, subcutaneous, intramuscular, intraarticular, intraarterial, intracerebral, intracerebellar, intrabronchial, intrathecal, topical, and aerosol route.
- Claim 34 (Currently amended): A method for reducing the deleterious effects of pathological free radical reactions in a mammal exposed to a caustic gas which afflicts the mammal with a disease or injury induced by pathological free radical reactions, the method comprising administering an effective amount of an amphipathic antioxidant composition comprising:
 - (i) a population of liposomes suitable for undergoing peroxidation and lysis; and
 - (ii) <u>at least two non-enzymatic amphipathic antioxidants selected from the group</u>
 <u>consisting of:</u> beta-carotene, vitamin E, vitamin C, glutathione, <u>N-acetyl-cysteine</u>,
 and niacin,₇

wherein the amphipathic antioxidant composition quenches free radicals and reduces the damage induced by the caustic gas exposure.

- Claim 35 (Previously presented): The method of claim 34, wherein said amphipathic antioxidant composition further comprises at least one trace metal.
- Claim 36 (Previously presented): The method of claim 35, wherein said at least one trace metal is selected from the group consisting of zinc, selenium, chromium, copper and manganese.

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Claim 37 (Currently amended): The method according to claim 35, wherein the composition includes an amount of beta-carotene, vitamin E, vitamin C, glutathione, niacin, and trace metals sufficient to deliver 0.0005-1.0 g beta-carotene per kg body weight, 0.001-10 g vitamin E per kg body weight, 0.001-2.0 g vitamin C per kg body weight, 0.001-2.0 g glutathione per kg body weight, 0.003-6.0 g N-acetyl-cysteine per kg body weight, 1-1000 mg niacin per day, and 1-1000 µg trace metals per day.

Claim 38 (Currently amended): The method according to claim 35, wherein the composition includes an amount of beta-carotene, vitamin E, vitamin C, glutathione, niacin, and trace metals sufficient to deliver 0.005-1.0 g beta-carotene per kg body weight, 0.01-1.0 g vitamin E per kg body weight, 0.01-1.0 g vitamin C per kg body weight, 0.01-1.0 g glutathione per kg body weight, 0.003-6.0 g N-acetyl-cysteine per kg body weight, 10-100 mg niacin per day, and 10-100 µg trace metals per day.

Claim 39 (Currently amended): The method according to claim 35, wherein the composition includes an amount of beta-carotene, vitamin E, vitamin C, and glutathione sufficient to deliver 0.05-1.0 g beta-carotene per kg body weight, 0.1-1.0 g vitamin E per kg body weight, 0.1-1.0 g vitamin C per kg body weight, 0.1-1.0 g glutathione per kg body weight, 0.003-6.0 g N-acetyl-cysteine per kg body weight, 10-100 mg niacin per day, and 10-100 g trace metals per day.